CMS Final Rule -- Changes to the Inpatient Only (IPO) List
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We have written extensively on the challenges facing SNFs in transitioning to a brave new world of payment and care models such as major health care payment innovations (e.g. bundling, ACOs) multiple quality programs, and various other market place developments. SNFs are involved in or impacted by such wide-ranging developments but also are more directly impacted by focused post-acute payment reform developments proposed by CMS and MedPAC, e.g., CMS' RCS -1 reform of the RUG system and MedPAC's proposed unified post- acute payment system.

However, there is also yet another category of transformation that SNFs must face and that is the evolution of payment systems other than its own that may have unintended consequences of depriving beneficiaries of necessary SNF post-acute care – collateral damage, so to speak. The current such issue is that of Inpatient Only procedures. Not only SNFs themselves but also ancillary providers such LTC pharmacies need to be vigilant about such developments in order to assist CMS in encompassing within its deliberations the need of the frail elderly to be able to choose SNF post-acute care to recover from invasive joint procedures.

The IPO Only list issues lay bare the complexities of providing high quality care to the frail elderly. Post-acute health care facilities such as SNFs play a crucial role in providing rehabilitation and close pharmaceutical attention to Medicare beneficiaries struggling to heal and regain mobility and strength after surgery. Thus, as CMS avers, careful patient selection and strict protocols for outpatient knee surgery is crucial to optimize both outpatient knee and hip replacement outcomes for inpatient and outpatient.

LTC pharmacies are part of the two strong foci of SNF post-acute care: rehabilitation therapy and drug therapy, needs that are very difficult to provide in a consistently safe and dependable manner in non-SNF environments. This need would appear to have minimized in the CMS decision making on the subject of permissible loci, paid for by Medicare, for knee and hip surgery.

The Proposed IPO Rule

On July 13, 2017, the Centers for Medicare & Medicaid Services (CMS) issued the Calendar Year (CY) 2018 Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Payment System proposed rule (CMS-1678-P) that includes updates to the 2018 rates and quality provisions, and proposes other policy changes.[1]

One critical policy is reflected in the Inpatient Only list (IPO). The IPO list indicates procedures that CMS has historically deemed can be performed only on an inpatient basis. [2] CMS has revisited this issue annually over the years, and each year it has used established criteria to review the Inpatient Only (IPO) list and determine whether or not any procedures should be removed from the list.

For CY 2018, CMS proposed to remove total **knee** arthroplasty (TKA) from the IPO list.[3] The CY 2018 OPPS/ASC proposed rule also sought comment regarding whether partial and total **hip** arthroplasty (PHA/THA) should also be removed from the IPO list for in a future rule. [4]

In the September issue of *LTCPharmacy.net*, we reviewed the proposed rule, focusing on TKA, and analyzed CMS' methodology for adding and or removing procedures, and the potential impact on beneficiaries, SNFs and hospitals of removing a procedure(s) from the list [5] we commented on the downside of removing TKA from the IPO List for beneficiaries seeking SNF post-acute care after TKA. Our concern was Medicare beneficiary access to needed SNF post-acute care and the inability to access SNF post-acute care without a 3 day stay in a hospital.

The Final CY 2018 IPO Rule

In the Final Rule, CMS proceeded to remove TKA, CPT code 27447, from the IPO list.[6] In addition, CMS precluded the Recovery Audit Contractors from reviewing TKA procedures for site of service issues for a period of two years to enable providers to develop experience with the removal of TKA. CMS also addressed the removal of PHA/THA from the IPO list but did not proceed with removal for CY 2018 leaving the issue to future rulemaking.

➢ *CMS Criteria for Removal from IPO List*

In the Final Rule for CY 2018, CMS used the existing five criteria, developed over the years, for reviewing procedures to determine whether or not they should be removed from the IPO list and assigned to an APC group (Ambulatory Payment Classification) for payment under the OPPS when provided in the hospital outpatient setting. [7] The criteria include the following:

1. Most outpatient departments are equipped to provide the services to the Medicare population;
2. The simplest procedure described by the code may be performed in most outpatient departments;
3. The procedure is related to codes that we have already removed from the IPO list;
4. A determination is made that the procedure is being performed in numerous hospitals on an outpatient basis; and
5. A determination is made that the procedure can be appropriately and safely performed in an ASC, and is on the list of approved ASC procedures or has been proposed by us for addition to the ASC list.

➢ *Public Comment on TKA Surgical Procedures and CMS Action*

CMS referred to the public comments on the removal of TKA from the IPO list. as "varied and nuanced." They were indeed varied reflecting strong opinions and concerns both for and against removal.

For example, those who favored removal expressed the belief that that continued refinements to the TKA surgical procedure allowed it to be performed safely on properly selected Medicare beneficiaries in the outpatient setting. A number of facilities indicated that they were currently performing TKA procedures on an outpatient basis in both the HOPD and ASC on non-Medicare patients. In addition, commenters who supported removing the TKA procedure from the IPO list also noted recent peer-reviewed publications that reported on investigations of the feasibility of outpatient TKA with positive results; that is, TKA outpatients did not experience higher rates of complications or readmissions in comparison to TKA inpatients.

Those not in favor of removal stated that the risk of postsurgical complications was too high for patients with the TKA procedure performed in the outpatient setting for the **Medicare population** and noted that patients appropriate for the TKA procedure performed on an outpatient basis tend to be younger, more active, have fewer complications, and have more at home support than most Medicare beneficiaries.

Commenters also believed there was insufficient research on the TKA procedure performed on an outpatient basis to definitively claim that the procedure could be safely performed in the outpatient setting. Further, some commenters stated that removing TKA from the IPO list could drive TKA to specific facilities based on cost alone, which could result in significant further stresses in isolated rural care settings.

Of critical importance to the care of Medicare beneficiaries is the concern of several commenters that regarding the ability of beneficiaries to access post-acute care for a TKA procedure at a skilled nursing facility (SNF). Medicare law requires that beneficiaries must have a prior inpatient hospital stay of no fewer than 3 consecutive days to be eligible for Medicare coverage of inpatient SNF care.

The commenters stated that discharging outpatient TKA patients without a 3-day stay and access to adequate rehabilitation would increase the likelihood of further medical concerns that may result in readmissions, which will result in higher expenses for the beneficiary, the Medicare program, and the hospital.

CMS nevertheless proceeded with removal of the TKA procedure described by CPT code 27447 based on various arguments including that:

- CPT code 27447 met a number of criteria for removal from the IPO list, including criteria 1, 2, and 4;

- CMS' review of the clinical characteristics of the TKA procedure and related evidence, including current length-of-stay (LOS) data for inpatient TKA procedures and peer reviewed literature related to outpatient TKA procedures – all supported removal;

- Consideration of input from the comment solicitation in the CY 2017 OPPS/ASC proposed rule and the professional opinions of orthopedic surgeons and CMS clinical advisors supported removal; and

- The recommendation from the summer 2016 meeting of the HOP Panel.

CMS emphasized that it expected providers to carefully develop evidence-based patient selection criteria to identify patients who are appropriate candidates for an outpatient TKA procedure as well as exclusionary criteria that would disqualify a patient from receiving an outpatient TKA procedure. CMS believes that the subset of Medicare beneficiaries who meet patient selection criteria for performance of the TKA procedure on an outpatient basis may have the procedure performed safely in the outpatient setting.

It might be quite a challenge to develop solid evidence-based selection criteria an environment where tensions are already rising between hospitals and orthopedic surgeons, according to senior health care analyst Harris Meyer. [8] Meyer comments in a June 2016 Blog that, building on advances in surgical technique, anesthesia and pain control, a small but growing number of surgeons around the country are moving more of their total joint replacement procedures out of the hospital, performing these lucrative operations in outpatient facilities.

- ***Public Comment on PHA/THA Surgical Procedures and CMS Action***

The scene, for and against IPO removal, now shifts to partial and total **hip** arthroplasty (PHA/THA . In the Proposed IPO rule, sought public comments on whether it should remove the procedures described by CPT codes 27125 and 27130 (partial and total **hip** arthroplasty (PHA/THA)) from the IPO list for in future rulemaking. [9]

In the Proposed Rule, CMS had specifically sought public comments on the following questions:

- Are most outpatient departments equipped to provide PHA and/or THA to some Medicare beneficiaries?
- Can the simplest procedure described by CPT codes 27125 and 27130 be performed in most outpatient departments?
- Are the procedures described by CPT codes 27125 and 27130 sufficiently related to or similar to other procedures we have already removed from the IPO list?
- How often is the procedure described by CPT codes 27125 and 27130 being performed on an outpatient basis (either in an HOPD or ASC) on non-Medicare patients?
- Would it be clinically appropriate for some Medicare beneficiaries in consultation with his or her surgeon and other members of the medical team to have the option of either a PHA or THA procedure as a hospital outpatient, which may or may not include a 24- hour period of recovery in the hospital after the operation?

In the Final Rule, CMS opines that the comments were diverse and some were similar to the comments received by CMS on its proposal to remove TKA from the IPO list. However, the public comments, as reported by CMS itself in the preamble, appeared to be running strongly **against removal** of the PHA and THA from the Inpatient Only list.[10]

Some commenters, including hospital systems and associations, as well as specialty societies and physicians, stated that it **would not be clinically appropriate** to remove PHA and THA from the IPO list, indicating that the patient safety profile of outpatient THA and PHA in the non- Medicare population is not well established.

Commenters representing orthopedic surgeons also stated that patients requiring a hemiarthroplasty (PHA) for fragility fractures are by nature higher risk, suffer more extensive comorbidities and require closer monitoring and preoperative optimization; therefore, it would not be medically appropriate to remove the PHA procedure from the IPO list.

Other commenters, including ambulatory surgery centers, physicians, and beneficiaries, supported the removal of PHA and THA from the IPO list. These commenters stated that the procedures were appropriate for certain Medicare beneficiaries and most outpatient departments are equipped to provide THA to some Medicare beneficiaries. They also referenced their own personal successful experiences with outpatient THA.

CMS may be leaning strongly toward removing PHA/THA procedures from the IPO list. Whether or not that is the case, providers and beneficiaries, both those who favor and do not favor removal from the IPO list, should be thoroughly engaged in developing **criteria** for determining whether a PHA/THA procedure could be safely performed in an outpatient environment.

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[1] CMS *Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs*, Proposed Rule for CY 2018, 82 Federal Register 33642, July 20, 2017.

[2]Before implementation of the Outpatient Prospective Payment System (OPPS) in August 2000, Medicare paid reasonable costs for services provided in the Hospital Outpatient Department (HOPD). Congress gave HHS broad authority to determine the services to be covered and paid for under the newly implemented OPPS.

[3]This is **knee surgery** related to the procedures described by the following codes from the IPO list for CY 2018: CPT code 27447 (Arthroplasty, knee, condyle and plateau; medical and lateral compartments with or without patella

resurfacing (total knee arthroplasty) and CPT code 55866 (Laparoscopy, surgical prostatectomy, retropubic radical, including nerve sparing, includes robotic assistance, when performed).

[4] **Partial Hip Arthoplasty (PHA) and Total Hip Anthroplasty (THA)** involves the following codes: Partial hip arthroplasty (PHA), CPT code 27125 (Hemiarthroplasty, hip, partial (eg, femoral stem prosthesis, bipolar arthroplasty), and total hip arthroplasty (THA) or total hip replacement, CPT code 27130 (Arthroplasty, acetabular and proximal femoral prosthetic replacement (total hip arthroplasty), with or without autograft or allograft), have traditionally been considered inpatient surgical procedures. The procedures were placed on the original IPO list in the CY 2001 OPPS final rule (65 FR 18780).

[5] *LTCNewsletter.net.*

[6] CMS *Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs*, Final Rule for CY 2018, 82 Federal Register 52356, November 13, 2017.

[7] Ibid at 52522.

[8] See Harris Meyer, Replacing joints faster, cheaper and better? June 4, 2016
http://www.modernhealthcare.com/article/20160604/MAGAZINE/306049986
and the September *LTCNewsletter.net* issue.

[9] 82 Federal Register 52356, at 52522. Note that CMS has applied a twostep approach to review of IPO procedures. In the year 2016, CMS asked for comment on removal of TKA from the IPO list. It did not propose the removal for CY 2017 but rather for CY 2018. Now in year 2017, CMS formally proposed the removal of TKA from the IPO list. In addition, in the same Federal register issuance, CMS, using the same type of two step approach has now asked for comments on the removal from the IPO list of PHA/THA via future rulemaking and did not propose removal for FY 2018.